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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/822,672	04/02/2001	Nabil Hanna	P 0280062 2000-30-0178A	9345
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909 7590 07/08/2003

PILLSBURY WINTHROP, LLP  
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MCLEAN, VA 22102

EXAMINER
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HELMS, LARRY RONALD

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 07/08/2003

14

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/822,672

Applicant(s)

HANNA, NABIL

Examiner

Larry R. Helms

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 21 April 2003.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-96 is/are pending in the application.
- 4a) Of the above claim(s) 1-73, 80 and 88 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 74-79, 81-87 and 89-96 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 12, 13.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

1. Claims 75, 81-82, 84, 86, 90 have been amended.
2. Claims 1-73, 80, 88, are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions. Applicant timely traversed the restriction (election) requirement in Paper No. 6.
3. Claims 74-79, 81-87, 89-96 are under examination with the species of an anti-CD20 antibody.
4. The text of those sections of Title 35 U.S.C. code not included in this office action can be found in a prior Office Action.

### ***Rejections Withdrawn***

5. The rejection of claims 81, 82, 84, 86, 90 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in view of arguments that present that the rituximab is ATCC 69119 (see page 10 of response of 4/21/03).
6. The rejection of claims 81, 82, 84, 86, and 90 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of treating B cell lymphoma in a patient by administration of the anti-CD20 antibody C2B8, with the appropriate evidence of public availability (see above), does not reasonably provide enablement for a method comprising administration of RITUXAN is withdrawn in view

Art Unit: 1642

that the claims are directed to rituximab which is produced from the ATCC transfectoma 69119.

***Response to Arguments***

7. The rejection of claims 81, 82, 84, 86, and 90 under 35 U.S.C. § 112, first paragraph, because the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention, because the specification does not provide evidence that the claimed biological materials are (1) known and readily available to the public; (2) reproducible from the written description is maintained.

The response filed 4/21/03 has been carefully considered but is deemed not to be persuasive. The response states that the rituximab is publicly available from ATCC and was given the ATCC number 69119 (see page 10 of response). In response to this argument, a search of the ATCC online catalog did not result in finding 69119. In addition, the response states that rituximab's amino acid sequence is disclosed in US Patent 5,736,137. In response to this argument, it is not clear whether the entire sequence of the antibody is disclosed and even though the claims are to the 69119 transfectoma, it is still unclear if all the assurances have been met.

8. The rejection of claims 74-79, 81-87, 89-96 under 35 U.S.C. 103(a) as being unpatentable over Alas et al (Blood 92:601A, 1998) and further in view of Levy et al (J.

Art Unit: 1642

Clin Invest 93:424-428, 1994) and Goldenberg (US Patent 6,183,744, filed 3/1998) and as evidenced by the specification is maintained.

The response filed 4/21/03 has been carefully considered but is deemed not to be persuasive. The response states Alas results do not suggest combining C2B8 and IL10 as a therapy having anti-cancer efficacy greater than either alone and the results teach away from the proposed combination (see page 11-12 of response). In response to this argument, the claims require anti-CD20 and an anti-IL10 antibody not C2B8 and IL10. In addition, Alas would teach away from the combination of C2B8 and IL10 because IL10 results in decreasing C2B8's ability to sensitize. The teachings of Alas does not teach away from C2B8 and anti-IL10 because addition of C2B8 resulted in downregulation of IL10 after 72 hours and it would be obvious to add anti-IL10 antibody to remove IL10 from the cells prior to the 72 hours.

The response states that Levy does not cure Alas and in Levy there is no data regarding the effect of anti-IL10 on cells absence exogenous IL10 (see page 12 of response). In response to this argument, it is unclear what this statement has to do with the argument and Levy clearly has a control in Figure 2 and text at page 427.

The response further states Goldenberg does not teach the combination of therapies which include IL10 antagonist (see page 12). In response to this argument, Goldenberg is cited as teaching multimodal therapy not the use of IL10 antagonist. It appears that the response is arguing the references separately and in response to applicant's arguments against the references individually, one cannot show non-obviousness by attacking references individually where the rejections are based on

Art Unit: 1642

combinations of references. In re Keller, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); In re Merck & Co., Inc., 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

The response further cites Bonnefoix et al as teaching the use of IL10 antagonist in cancer therapy was controversial (see page 12-13 of response). In response to this argument, Bonnefoix et al does not teach any IL10 antagonists and it is clear from the prior art in the rejection cited that IL10 is important for cancer therapy and regulates bcl-2.

Therefore, it would have been obvious to combine an anti-IL-10 antibody wherein removal of IL-10 results in abolishing the effects of bcl-2 by blocking cell death and adding C2B7 to sensitize the 2F7 cells and adding a chemotherapeutic because combination therapy has been shown to treat cancers effectively.

Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references.

### ***Conclusion***

9. No claim is allowed.

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

Art Unit: 1642

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Larry R. Helms, Ph.D, whose telephone number is (703) 306-5879. The examiner can normally be reached on Monday through Friday from 7:00 am to 4:30 pm, with alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

12. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 308-4242.

Respectfully,

Application/Control Number: 09/822,672

Page 7

Art Unit: 1642

Larry R. Helms Ph.D.

703-306-5879

A handwritten signature in black ink, appearing to be 'L. Helms', located to the right of the contact information.